K112832

510(k) Summary

DEC - 5 2011

1. **Date of Preparation:** September 21, 2011

2. **Applicant Device Information:**

Device Name: Eye Care and Cure Contact Lens Case

Common Name: Contact Lens Case

Classification Name: Case, Contact Lens

Device Class: Contact lens carrying cases are considered Class II Medical Devices by the FDA, although not formally classified at this time.

Recommended Classification Regulation Number: 21 CFR §886.5928

Product Code: LRX

Predicate Devices:

The following devices have been identified as the predicate devices for the Eye Care and Cure contact lens case:

Predicate Device:
i-Promotions Contact Lens Case (K042578)
i-Promotions, Inc.
9522 Gravois Rd.
St. Louis, MO 63123

Predicate Device:
Pelican Contact Lens Case (K030987)
Pelican Products, Inc.
2248 Highway 43 North
Pelhatchie, MS 39145

Non-Sterile:
The Eye Care and Cure Contact Lens Case is a non-sterile device.

Packaging/Labeling:
The contact cases will be sold in bags of 100, including 100 individual labels to be distributed by eye care professionals to contact lens case users together with the case.

Device Description and Intended Use:

The Eye Care and Cure Contact Lens Case consists of a lens case base with adjoining dual walls for the containment of fluid and separate integral hinged self-sealing caps.

The Eye Care and Cure Contact Lens Case is intended for storage during disinfection of soft, rigid gas permeable or hard contact lenses. It is to be used for chemical disinfection only. It is not intended to be use with heat disinfection.

Material:
Polyethylene 9931 Low Density (2380) is the same material used by predicate i-Promotions (K042578) with an established history of safe and effective use as a non body contacting, non implanted medical device for holding a contact lens.

3. Submitter Information

Manufacturer:
Eye Care and Cure Corporation
4646 S. Overland Dr.
Tucson, AZ 85714
Establishment Registration: 2085143
Owner/Operator Number: 9044582

Contact Person for Submission:
Lindy van Dalen
Regional Director
Eye Care and Cure
4646 S. Overland Drive
Tucson, AZ 85714
Phone: (520) 321-1262
Email: lindy.vandalen@eyecareandcure.com

5. Device Description
The Eye Care and Cure Contact Lens Case is to be used for the storage during chemical disinfection of soft, rigid gas permeable or hard contact lenses. The case is to be used during chemical disinfection only and is not to be used with heat disinfection devices.

The Eye Care and Cure Contact Lens Case is polyethylene and consists of a two adjoining wells, with hinged self-sealing caps, in which contact lenses are immersed in fluid. Rub and rinse your contact lenses as directed by your eye care professional. The two adjoining wells of the Eye Care and Cure Contact Lens Case each have a capacity of 1.0ml. This is sufficient capacity to fully immerse a contact lens when the well is filled with chemical under normal use conditions. The inner height of the well measures 8mm.

The Eye Care and Cure Contact Lens Case is made of Dow Chemical Company Low Density Polyethylene, Dow Product #9931. No colorant will be added.

6. Substantial Equivalence Determination

	Applicant Device	Predicate Device	Predicate Device
1. Classification			
Device Name	Eye Care and Cure Contact Lens Case	i-Promotions Contact Lens Case K042578	Pelican Products, Inc. #500/600 (deep well lens case with integral lids) K030987
Classification Name	Case, Contact Lens	Case, Contact Lens	Case, Contact Lens
Product Code	LRX	LRX	LRX
Comparison Statement	**The applicant device has the same classification as the predicate devices.**		
2. Intended Use			
Intended Use	The applicant device is to be used for the storage during disinfection of soft, rigid gas permeable or hard contact lenses. The case is to be used during chemical disinfection only and is not to be used with heat.	The predicate device is intended for storage during disinfection of soft, rigid gas permeable or hard contact lenses. Not to be used with heat disinfection. Use only with chemical disinfection.	The predicate device is intended for the storage of soft (hydrophilic)/rigid gas permeable and hard contact lenses during chemical disinfection. Not to be used for heat disinfection.
Indications	Storage and disinfection of soft, rigid gas permeable or hard contact lenses	Storage and disinfection of soft, rigid gas permeable or hard contact lenses	Storage of soft (hydrophilic)/rigid gas permeable and hard contact lenses during chemical disinfection
Comparison Statement	**The applicant device has the same intended use as the predicate devices.**		
3. Design/Material			
Design	Two adjoining wells, with	Two adjoining wells with	Two adjoining wells with integral

	integral hinged caps, into which lenses are immersed.	integral hinged cap into which respective lenses are immersed.	lids into which lenses are immersed.
Material	Dow Chemical Company Low Density Polyethylene, Dow Product #9931	Dow Chemical Company Low Density Polyethylene, Dow Product #9931	
Comparison Statement	**The applicant device has a similar product design and is made of the same material as the predicate devices.**		
4. Effectiveness			
Effectiveness	The applicant device has two adjoining wells with sufficient capacity to allow for a contact lens to be fully immersed.	The predicate device has two adjoining wells into which respective lenses are immersed.	The predicate device has two adjoining wells into which lenses are immersed
Comparison Statement	**The applicant device has the same performance effectiveness as the predicate devices.**		
5. Safety	**Applicant Device**	**Predicate Device**	
Material	Dow Chemical Company Low Density Polyethylene, Dow Product #9931	Dow Chemical Company Low Density Polyethylene, Dow Product #9931	

	No tests conducted as material is the same as the material used by the predicate device.	1. *In Vitro* Cyto-Toxicity: No Cyto-toxicity 2. Delayed-Type Hypersensitivity: No delayed dermal contact sensitization 3. Eye Irritation: No intracutaneous reactivity 4. Systemic Toxicity: No systemic toxicity
Comparison Statement	**The applicant device is made of the same material as the predicate device and therefore has the same performance safety as the predicate device.**	
6. Labeling & Packaging	Applicant Device	Predicate Device
	Refers to product as Eye Care and Cure contact lens case; instructs patients to clean lens case as recommended by the patient's eye care practitioner.	Refers to product as i-Promotions contact lens case; instructs patients to clean lens case with disinfecting solution recommended for this purpose.

Conclusion:

The applicant device has the same classification, same intended use and indications, similar product design, same materials, same performance effectiveness and the same performance safety as the predicate device. There are no new changes to raise new issues of safety and effectiveness. Therefore, therefore the applicant device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 5 2011

Eye Care and Cure Corp.
c/o Lindy van Dalen
Regional Director
4646 S. Overland Dr.
Tucson, AZ 85714

Re: K112832
Trade/Device Name: Eye Care and Cure Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: September 21, 2011
Received: September 29, 2011

Dear Ms. van Dalen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part

807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesica Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510 (k) Number: K112832

Device Name: Eye Care and Cure Contact Lens Case

Indications for Use:

The storage and disinfection of soft, rigid gas permeable or hard contact lenses.

For use during chemical disinfection only. Not to be used with heat.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:_____ or Over-The-Counter Use ✓
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and ENT Devices
510(k) Number